

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

-----X	
<b>THE PROCTER &amp; GAMBLE COMPANY,</b>	)
	)
<b>Plaintiff,</b>	)
	) <b>Civil Action No. 07-Civ-8379 (RJS)</b>
<b>v.</b>	)
	) <b>ECF Case</b>
<b>ULTREO, INC.,</b>	)
	)
<b>Defendant.</b>	)
-----X	

**MEMORANDUM OF LAW IN OPPOSITION TO  
THE PROCTER & GAMBLE COMPANY'S  
MOTION FOR A PRELIMINARY INJUNCTION**

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**INTRODUCTION**

The Procter & Gamble Company's ("P&G") Complaint is a transparent and improper attempt to prevent Ultreo, Inc. ("Ultreo"), a fledgling competitor, from entering the premium power toothbrush market. P&G's motion for a preliminary injunction is not well-founded factually or legally, and should be denied.

P&G is a repeat offender when it comes to using litigation as a means to achieve anti-competitive ends. In *P&G Pharmaceuticals, Inc. v. Hoffmann-La Roche Inc.*, No. 06-Civ-0034, 2006 WL 2588002, \*10 (S.D.N.Y. Sept. 6, 2006) (Crotty, J), this Court found that P&G's motive in seeking to enjoin a competitor's advertising was to stop a potential new market entrant in "the starting blocks," stating as follows: "P&G's chief concern is . . . not public health and safety, but rather its market share." *Id.*

P&G's cries of "false advertising" in this case against Ultreo are more of the same. P&G's Complaint has nothing to do with public health or fairness to consumers, and everything to do with P&G's improper maintenance of its robust market share. Indeed, P&G confidential documents obtained during discovery reveal P&G's true colors. For instance, an internal P&G e-mail dated February 13, 2007 sounded the initial alarm at P&G as follows:

Contains Information Designated As  
"Confidential" Pursuant To November 9,  
2007 Stipulated Confidentiality Order In  
This Action

**REDACTED**

*See Declaration of Jack Gallagher ¶ 24 (PG006813-16 at PG006814) (boldface added).*

Like P&G's motives, the merits of P&G's false advertising allegations also do not withstand scrutiny. Although P&G argues that all advertising claims touting each attribute of a power toothbrush must be based on clinical test results, no such industry or governmental standard exists. To the contrary, the established industry standard is that laboratory tests using



scientifically reliable methods are perfectly acceptable, provided that the test results are not misstated by the advertiser. Indeed, the leaders in this market, P&G and Philips Oral Healthcare ("Philips"), both make advertising claims for oral care products based on laboratory results.

Ultreo has done the same. Ultreo has conducted reliable laboratory tests that demonstrate the efficacy of its toothbrush, and has faithfully reported those results. Those tests demonstrate that the Ultreo's combined use of ultrasound technology and sonic bristle action is effective in removing plaque bacteria from model dental surfaces without physical contact by the bristles (the "UW Study"). This should come as no surprise to P&G, because its own confidential laboratory research, produced in discovery in this litigation, confirms the efficacy of ultrasound as a means of removing plaque bacteria without bristle contact. *See* Declaration of James Christopher McInnes ¶¶ 33-35, 44.

Moreover, Ultreo's advertising claim to professionals that a power toothbrush can remove plaque bacteria beyond the reach of its bristles is hardly unique to Ultreo. Philips has long advertised that its Sonicare power toothbrush ("Sonicare"), by generating dynamic fluid forces, cleans plaque beyond the reach of its bristles. Philips has relied on identical laboratory studies in making these claims to dental professionals. Moreover, in 2004, when P&G formed an alliance with Philips to jointly market a Sonicare power toothbrush, P&G joined with Philips in publicly proclaiming to the dental industry that the Sonicare removed plaque beyond the bristles. P&G relied on the same type of in vitro laboratory studies it now argues are insufficient to support this type of advertising claim.

As for Ultreo's advertising claims to consumers, Ultreo is not making any claim regarding the specific plaque cleaning benefits of the ultrasound component of the Ultreo. To be sure, P&G argues that Ultreo is making such an implied claim. Yet, the only basis for this argument is a patently flawed consumer survey tricked up solely for the purpose of this lawsuit.

P&G's survey should be given no weight because it inexplicably failed to include a control group, used leading questions, and failed to comply with virtually all the well-established standards for reliable consumer survey results. In any event, even if consumers are somehow taking away such an implied claim, Ultreo's reliable laboratory tests show that the claim is true – ultrasound does help remove plaque bacteria.<sup>1</sup>

P&G has also failed to demonstrate that it will suffer any irreparable harm in the absence of the drastic relief it seeks. P&G has a huge market share; Ultreo has a miniscule (less than 1%) share. P&G has utterly failed to demonstrate a causal connection between any allegedly false advertising and the concomitant harm to P&G. P&G, which waited more than six full months before filing this action, cannot argue credibly that it is suffering immediate irreparable harm. P&G has an adequate remedy at law.

The balance of the equities also weighs decidedly in favor of Ultreo. Any alleged impact on P&G from Ultreo's actions amounts to little more than a blip on the proverbial radar screen of a multinational empire whose sales, according to P&G, total \$76 billion worldwide.

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This Action

**REDACTED**

*See*

Gallagher Decl. ¶¶ 22-33. For all these reasons, P&G's motion should be denied.

### **FACTS**

#### **A. Sonicare Establishes The Efficacy Of Ultrasound In Removing Plaque.**

The Optiva Corporation ("Optiva") introduced the Sonicare toothbrush in the early 1990s. The Sonicare combines the elements of direct mechanical brushing with fluid dynamic forces

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<sup>1</sup> Furthermore, to ensure there is not even the potential for confusion, Ultreo is taking the voluntary step of including in its consumer packaging and advertising materials the express statement that "ultrasound efficacy is based on laboratory studies." Gallagher Decl. ¶ 39. Under these circumstances, no person of reasonable intelligence can claim to be confused or misled.

generated by increased bristle velocity and frequency. Its core marketing claim to dental professionals has been, and still is, that those fluid forces are able to remove plaque bacteria beyond the reach of the bristles. Notably, Philips has always supported these "beyond-the-bristles" claims with laboratory studies. *See, e.g.*, Gallagher Decl. ¶¶ 2, 47; Declaration of Joel Berg ¶¶ 12-21; McInnes Decl. ¶¶ 22-30.

The Sonicare has been an incredibly successful product. In 2000, Optiva was acquired by the large conglomerate Philips. Today, as P&G's Wayne Randall admits in his declaration, Philips has a 62% share of the market for premium power toothbrushes. As described below, the standard that Philips, the current market leader, has set for the industry includes the making of product claims to dental professionals based on results obtained in laboratory (in vitro) studies.

**B. Ultreo Attempts To Enter The Market.**

Ultreo is a small company located in Redmond, Washington, that manufactures and sells a single product – the Ultreo power toothbrush. It was formed in 2003 by former scientists, engineers and executives of Optiva. Between 2003 and 2006, Ultreo and academicians at the University of Washington's ("UW") Center for Industrial and Medical Ultrasound developed a product that combines ultrasound technology with a sonic power toothbrush. The objective was to design a power toothbrush that would generate ultrasound-activated bubbles that could augment the mechanical cleaning capabilities of the toothbrush. Numerous prototypes were tested over a 3½ year period, at a cost in excess of \$5.5 million. Gallagher Decl. ¶¶ 5-13; McInnes Decl. ¶¶ 6-8.

The novelty of the Ultreo is confirmed by the fact that it and UW were issued patents by the U.S. Patent and Trademark Office, and that Ultreo was awarded several research grants from the Washington Technology Center and the prestigious National Institutes of Health after those bodies had conducted a thorough review and approval of Ultreo's testing protocols. By February

2007, Ultreo finally had a product that could be brought to market. Gallagher Decl. ¶¶ 11-14.

Ultreo has marketed its toothbrush to dental professionals through advertising in professional journals and by direct marketing and has been remarkably well-received by the professional community. To date, a majority of Ultreo's sales have been to dental professionals who have purchased the product for themselves or their patients. Gallagher Decl. ¶¶ 14-16.

Ultreo also sells its product to consumers via Internet retailers, to specialty stores, such as The Sharper Image, catalog stores, such as Hammacher Schlemmer, and major retailers such as Macy's and Bloomingdale's. Consumer reactions based on use of the Ultreo have also been extremely positive. A Consumer Use Survey, whose participants consisted mostly of Oral-B and Sonicare rechargeable power toothbrush users, found, among other things, that eight out of ten of all users surveyed said that they would switch to the Ultreo. Significantly, this response was based on actual home usage of the Ultreo for thirty days. Gallagher Decl. ¶¶ 17-21.

Clinical studies conducted with independent scientists have shown that the Ultreo is safe and efficacious in removing plaque and stains and in reducing gingivitis. Laboratory studies conducted by Ultreo and UW have shown that the Ultreo removes plaque bacteria from model dental surfaces in the absence of physical bristle contact. McInnes Decl. ¶¶ 9-21; Berg Decl. ¶¶ 7-8, 35.

#### **C. Procter & Gamble Reacts To The Competition.**

P&G is the manufacturer of the Oral-B brand of power toothbrushes. It controls 38% of the market for premium power toothbrushes. Prior to acquiring the Oral-B brand in 2005, P&G jointly marketed a product with Philips that combined a Sonicare toothbrush with a Crest brand toothpaste dispenser incorporated within the brush (the "IntelliClean System").

In connection with the IntelliClean System launch in 2004, P&G and Philips jointly published and disseminated to the dental community a "Compendium" of clinical and laboratory

research regarding the product. The Compendium prominently discloses on its cover that the research reflected therein was "[s]upported by . . . The Procter & Gamble Company." It is replete with articles authored by P&G scientists that state that the Sonicare toothbrush has been proven to remove plaque bacteria beyond the bristles, and with supporting citations that refer to in vitro laboratory studies that are virtually identical in design to Ultreo's UW Study. McInnes Decl. ¶¶ 24-30; Berg ¶ 21.

Indeed, the lead article in the Compendium, which is co-authored by a P&G Senior Scientist, explains that the Sonicare toothbrush "creates dynamic fluid activity in the mouth," and that "[a]ccording to in vitro studies . . . such fluid activity can remove plaque from beyond the reach of the bristles significantly better than a rotational-oscillation power toothbrush." McInnes Decl., ¶ 27, Exh. H at PG007059. That same article states that, like other Sonicare toothbrushes, the IntelliClean System "has also been shown in vitro . . . to exhibit 'beyond-the-bristles' cleaning and to be gentle on dentin, significantly more so than the Oral-B ProfessionalCare 7000, a leading rotational oscillation toothbrush." *Id.* at PG007061. Notably, nowhere in that article do the authors state that the results of the laboratory studies upon which they have relied must be corroborated by clinical studies. Thus, at a time when its financial interests were different, P&G made the very claims that it now attacks as false, and relied upon the very science it now claims is inadequate. Yet, the only thing that has changed between then and now is that P&G acquired ownership of the "rotational-oscillation toothbrush" that it pronounced as inferior in 2004.

### **ARGUMENT**

A party seeking a preliminary injunction must demonstrate: (1) either (a) a likelihood of success on the merits, or (b) sufficiently serious questions to make them fair ground for litigation, with a balance of hardships tipping decidedly in the moving party's favor; *and* (2) irreparable harm. *See Hoffmann-La Roche*, 2006 WL 2588002, at \*25; *Clauson v. Eslinger*, 455



F. Supp. 2d 256, 259 (S.D.N.Y. 2006). P&G's burden is a demanding one. A preliminary injunction is an "extraordinary and drastic measure" that is not routinely granted. *ImOn, Inc. v. ImaginOn, Inc.*, 90 F. Supp. 2d 345, 349 (S.D.N.Y. 2000).

**I. P&G IS UNLIKELY TO SUCCEED ON THE MERITS OF ITS CLAIMS.**

To prove the falsity of a statement for the purposes of a Lanham Act false advertising claim, P&G must prove that either the advertisement is literally false, or that the advertisement, while literally true, is likely to mislead a substantial number of consumers. *Chamilia, LLC v. Pandora Jewelry, LLC*, No. 04-CV-6017, 2007 WL 2781246, at \*6 (S.D.N.Y. Sept. 24, 2007).

**A. P&G Cannot Prove That Ultreo's Advertising Claims Are Literally False.**

Advertising claims that are alleged to be literally false can include "establishment" claims, which are claims based upon scientific studies or tests. See *Hoffmann-La Roche*, 2006 WL 2588002, at \*\*30-31. In order to establish the literal falsity of an establishment claim, the burden is on P&G to demonstrate that Ultreo's tests are "not *sufficiently reliable* to permit one to conclude with *reasonable certainty* that they established the proposition for which they were cited." *The P&G Co. v. Chesebrough-Pond's, Inc.*, 747 F.2d 114, 119 (2d Cir. 1984) (emphases supplied); accord *Glaxo Warner-Lambert OTC G.P. v. Johnson & Johnson Merck Consumer Pharms. Co.*, 935 F. Supp. 327, 329 (S.D.N.Y. 1996); *Nationwide Tarps, Inc. v. Midwest Canvas Corp.*, 228 F. Supp. 2d 202, 210 (N.D.N.Y. 2002). The tests need not be "perfect." Minor methodological flaws will not invalidate a scientific study. See *L&F Prods. v. The P&G Co.*, 845 F. Supp. 984, 1001 (S.D.N.Y. 1994), *aff'd*, 45 F.3d 709 (2d Cir. 1995).

P&G challenges as expressly false certain Ultreo advertising claims, made to dental professionals, that the Ultreo's ultrasound technology can remove plaque bacteria and enhance

the product's ability to remove such bacteria as shown in laboratory tests.<sup>2</sup> P&G Brief at 15-16. P&G alleges that these claims are expressly false because they are supported by laboratory (in vitro) studies, instead of clinical (in vivo) studies. P&G's position is unfounded and incoherent.

No industry, governmental, or judicial standard exists requiring that all advertising statements about each component of an oral healthcare product be supported by clinical studies. Berg Decl. ¶¶ 7-11. Indeed, none of the cases cited by P&G involves oral care products. P&G Brief at 16-17. *Church & Dwight Co. v. S.C. Johnson & Son, Inc.*, 873 F. Supp. 893 (D.N.J. 1994), involved carpet deodorizers, a product that could not be tested in humans. *U.S. v. Premo Pharmaceutical Labs, Inc.*, 511 F. Supp. 958 (D.N.J. 1981), a case not involving the Lanham Act, involved the safety of a pharmaceutical product that is required by federal regulation to be established in a clinical trial. *SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co.*, 906 F. Supp. 178 (S.D.N.Y. 1995), *aff'd*, 100 F.3d 943 (2d Cir. 1996), involving antacids, did not establish any broad principles regarding the types of tests that must be used to support advertising claims. It merely refused to credit an advertiser's tests that were flatly contradicted by its own internal data. Moreover, none of these cases purports to endorse, let alone address, P&G's absurd contention that one must isolate and test separately in a clinical setting each and every component of a given product.<sup>3</sup>

Other Lanham Act cases have held that advertising claims may be made on the basis of laboratory tests, including ones made by P&G. In *L&F Products v. The P&G Company*, 845 F.

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<sup>2</sup> P&G mixes and matches claims that Ultreo makes to *dental professionals* with those it makes to *consumers*. P&G has also made allegations with respect to certain claims that Ultreo no longer makes. Gallagher Decl. ¶¶ 34-46. Annexed hereto as Exhibit A is a chart that sets forth, as to representative claims challenged in P&G's papers, whether that advertising claim is currently being made by Ultreo, and whether that claim is made to professionals or consumers.

<sup>3</sup> P&G does not claim that Ultreo lacks clinical studies supporting the general efficacy and safety of its toothbrush. Those studies are described in the Declaration of Dr. McInnes ¶¶ 9-15.



Supp. at 992-93, the plaintiff challenged P&G's commercials about its bathroom cleaner's effectiveness. This Court refused to grant a preliminary injunction, noting that P&G was justified in relying upon its laboratory studies. *See also Playtex Prods., Inc. v. Gerber Prods. Co.*, 981 F. Supp. 827, 828-30 (S.D.N.Y. 1997) (denying request for a preliminary injunction where claim was supported by defendant's laboratory testing); *Spalding Sports Worldwide, Inc. v. Wilson Sporting Goods Co.*, 198 F. Supp. 2d 59, 68 (D. Mass. 2002) (denying request for preliminary injunction where laboratory test results supported advertising claim).

The Second Circuit has set no bright-line rule here. It instructs the fact-finder to consider all circumstances, including: "the [product's] state of the testing art, the existence and feasibility of superior procedures, the objectivity and skill of the persons conducting the tests, the accuracy of their reports, and the results of other pertinent tests." *Chesebrough-Pond's*, 747 F.2d at 119.

#### **1. Ultreo Conducts State-Of-The-Art Studies.**

The use of laboratory studies in the oral care field is well-established. Indeed, they are widely used in the dental health research community to support specific product claims.<sup>4</sup> For instance, Philips claims in its advertising to dental professionals that the dynamic fluid forces of the Sonicare cleans plaque beyond the reach of its bristles. Philips substantiates its "beyond-the-bristles" claims with laboratory studies that are virtually identical to the UW Study relied upon by Ultreo. Berg Decl. ¶¶ 11-21; McInnes Decl. ¶¶ 16-30.

P&G has also publicly affirmed Philips' beyond-the-bristles claims and has embraced the supporting laboratory studies in its October 2004 Compendium regarding the IntelliClean

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<sup>4</sup> When Ultreo makes these claims to professionals, it plainly discloses in the advertisement that the claim is supported by a laboratory study. Gallagher Decl. ¶ 45; Berg Decl. ¶ 39. Courts have endorsed this method of disclosure. *Consumers Union of U.S., Inc. v. Gen. Signal Corp.*, 724 F.2d 1044, 1052-53 (2d Cir. 1983); *Thompson Med. Co. v. CIBA-GEIGY Corp.*, 643 F. Supp. 1190, 1199-1200 (S.D.N.Y. 1986).

System. In that published research, P&G scientists repeatedly refer to Sonicare's proven ability – based on laboratory tests – to remove more plaque biofilm beyond the bristles than an Oral-B toothbrush. Indeed, the Compendium expressly states that "in vitro test methods applied here . . . provide methods of assessment of product efficacy representative of what would be found in the oral cavity." *See* McInnes Decl. ¶¶ 24-30 and Exhibit H at PG007104; Berg Decl. ¶ 21.

Even today, P&G makes advertising claims to consumers regarding the bacteria-reducing potential of its oral care products based on the results of laboratory studies. For instance, P&G claims that its Crest ProHealth Rinse kills "99 percent of common germs that can cause plaque, gingivitis and bad breath" – based on laboratory testing. And, P&G claims that its Crest toothpaste possesses "extra whitening power" as demonstrated by lab tests. Gallagher Decl. ¶ 48. In short, P&G relies upon lab studies to support advertising claims when it deems it prudent to do so, but seeks to impose upon Ultreo a standard to which P&G does not adhere.

**2. Current Clinical Plaque-Removal Study Methods Are Not Designed To Isolate And Test The Efficacy Of Integrated Technologies.**

Traditional, visible plaque-removal studies are designed to measure the general performance of a toothbrush. They are not designed to isolate and assess the relative capabilities of combined technologies in a product. Indeed, these tests are simply not sufficiently rigorous or precise enough to be able to detect, through a post-treatment visual examination, whether there are any additional benefits achieved from non-mechanical aspects of power toothbrushes, such as those employed by the Sonicare or the Ultreo. Berg Decl. ¶¶ 16-18; McInnes Decl. ¶¶ 56-59.

Philips recognizes this limitation. While it has conducted or sponsored a number of clinical studies that evaluate the general efficacy of its product as a complete integrated product that utilizes *both* mechanical brushing action and dynamic fluid activity, it has never published any clinical study that isolates the benefits of its dynamic fluid forces. Instead, laboratory

studies are the sole basis upon which Philips relies to make beyond-the-bristles claims, or to extol the cleaning benefits of the Sonicare's hydrodynamic fluid action. Berg Decl. ¶¶ 15-20.

Similarly, P&G markets a combined technology product, an oral irrigator known as the "Oxyjet." P&G claims that the Oxyjet is the "world's first oral irrigator with unique micro-bubble technology," and that "it mixes air and water, then pressurizes it to form millions of long-lasting micro-bubbles designed to attack plaque bacteria." Yet, P&G has not conducted any clinical study that purports to isolate the "microbubble technology" from the fluid streaming forces of the irrigator. Berg Decl. ¶¶ 41-46. That has not stopped P&G from telling consumers that the microbubbles "attack plaque bacteria."<sup>5</sup>

Furthermore, the dental research community has grown skeptical of corporate-sponsored clinical comparative plaque-removal studies because large corporations with vast resources like P&G can – and apparently do – manipulate testing methodologies to achieve desired results.

For instance, P&G's Oral-B website discloses the existence of 40 clinical studies comparing an Oral-B power toothbrush to a competing power or manual toothbrush. Except for one instance where there was no significant difference between the tested toothbrushes, P&G claims that its record is an extraordinary 40-0 in clinical comparative testing. As for Philips, it discloses 13 clinical studies comparing the Sonicare with a competing power or manual toothbrush, and claims to have an undefeated 13-0 record. More importantly, both P&G and Philips have published clinical test results purporting to show that its brush outperforms the other. These dubious and irreconcilable results have understandably led members of the research

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<sup>5</sup> P&G also claims that its Oral-B Triumph and ProfessionalCare 8000 Series are the "only" power toothbrushes that combine a rotating or oscillating brushhead movement, and an in-and-out pulsating movement. However, its website discloses no clinical study that shows that the discrete in-and-out pulsating feature enhances the plaque removal capabilities of these current products. Berg Decl. ¶ 42.

community to question the importance and value of comparative clinical research. Berg Decl. ¶¶ 23-27.

**3. The UW Test Was Conducted By Objective, Experienced Professionals.**

Ultreo's laboratory test was conducted by experienced dental researchers from the University of Washington. Dr. Beth Hacker and Teresa Oswald are two of the co-authors of the UW Study. Dr. Hacker is an experienced research scientist. Ms. Oswald is a microbiologist. Neither of these individuals has any financial stake in Ultreo. P&G's study, on the other hand, was conducted entirely in-house by P&G personnel on unblinded P&G employees. McInnes Decl. ¶¶ 18, 47, 51.

**4. The UW Test Was Properly Conducted And Its Results Were Accurately Reported.**

Dr. McInnes explains in his Declaration how the UW Study was conducted and how the results were recorded. Dr. Berg opines that the UW Study was validly conducted and is reliable proof that the Ultreo's ultrasound removes plaque bacteria in the absence of bristle contact. McInnes Decl. ¶¶ 16-21, 36-46; Berg Decl. ¶¶ 28-35. Indeed, the ultrasonic plaque bacteria cleaning action of the Ultreo has now been captured on film. Professor Lawrence Crum, a leading national expert on ultrasound, and his staff have captured that action on high speed film so that the plaque bacteria removal effects of the ultrasonic activation of bubbles is visually identifiable. Decl. of Lawrence A. Crum ¶¶ 9-22 and Movie Videos 1-3 at Exhibit B (on CD).

Documents recently produced to Ultreo by P&G during discovery in this case show that P&G replicated the UW Study and obtained the same result. The ultrasound-activated Ultreo removed significant quantities of plaque bacteria without bristle contact, and significantly more than the Oral-B power toothbrush or the Ultreo with the ultrasound disabled. McInnes Decl. ¶¶ 34-35. This result unquestionably establishes that the UW Study was properly conducted, and that its reported results are accurate.

**5. P&G's Clinical Study Is Deficient In Several Major Respects.**

The clinical study conducted by P&G's employees (using unblinded P&G employees as subjects), fails to demonstrate anything about the contribution of *ultrasound* to the Ultreo's plaque removal capabilities. It did not compare the Ultreo with its *ultrasound* component *activated*, to the Ultreo with its ultrasound component *deactivated*. Instead, it inexplicably compared the Ultreo with its power on (sonic bristle and ultrasound powers on) to the Ultreo with its power off, used as a manual toothbrush. McInnes Dec. ¶¶ 47-53; Berg Decl. ¶¶ 36-38. Significantly, the fact that P&G's Clinical Study exclusively involved biased P&G employees as subjects became known only through discovery in this case. That fact is not disclosed anywhere in the article P&G submitted for publication or in the Affidavit of Dr. Biesbrock.

The study also employed a bizarre protocol in which a hygienist held the Ultreo brushhead stationary at a 1-3 millimeter distance from the tooth surfaces of the subject. The fundamental problem with this approach is that the protocol ensures that there will not be any fluid coupling, and absent that, the ultrasound cannot drive bubbles onto the tooth surface so that it can help clean teeth. The test is seriously flawed in this respect. Indeed, it employs an unprecedented and unproven protocol that was obviously created to achieve the results and litigation ends that P&G desired. McInnes Decl. ¶¶ 49-50; Berg Decl. ¶ 36.<sup>6</sup>

P&G erroneously contends that a recent clinical study by Philips, which purports to measure the plaque removal capabilities of the Sonicare FlexCare and the Ultreo, further supports P&G's clinical study. The only information P&G provides with respect to this study is a two-page abstract released by Philips. P&G has not produced any data describing how the

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<sup>6</sup> The P&G clinical study also purports to show that the Ultreo performs better when used as a manual toothbrush. This result is inconsistent with Oral-B's own clinical research which indicates that its power toothbrushes consistently outperform manual toothbrushes. Berg Decl. ¶ 38; McInnes Decl. ¶ 52.



study was conducted. In the absence of this key data, P&G cannot opine on the validity of Philips' purported test results. McInnes Decl. ¶¶ 54-59.

In sum, all of the factors enunciated in *Chesebrough-Pond's* strongly weigh in favor of the validity of the UW Study. P&G's attack on Ultreo's establishment claim must, therefore, fail, particularly when considering the target audience for Ultreo's claim – dental professionals.

Courts take into account the sophistication of a target audience in considering the veracity of advertising claims. In *Hoffmann-La Roche*, 2006 WL 2588002, at \*\*29-31, this Court found that P&G had not established a likelihood of success with respect to its claim that the defendant's sales personnel made a literally false establishment claim to physicians when they conducted a post-hoc analysis of the results from a study. The Court rejected P&G's argument, holding that "the sophistication of the target audience is one that is fully capable of discerning that it was being presented with a 'post-hoc' analysis" of study data. Similarly, in *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 229-30 (3d Cir. 1990), the court held that certain claims made in physician circulars were not misleading, holding that,

[c]ontext can often be important in discerning the message conveyed and this is particularly true where, as here, the target of the advertising is not the consuming public but a more well informed and sophisticated audience . . . Hence, **a target audience's special knowledge of a class of products is highly relevant to any claim that it was misled by an advertisement for such a product.** [The plaintiff] never advanced any hard evidence that pediatricians would be misled by [the defendant's] information sheets or that they would believe that the assertions contained therein were supported by a greater degree of testing data than [the defendant] actually had compiled.

*Id.* (internal quotation omitted) (boldface added). Here, the dental professionals viewing Ultreo's advertisements know the difference between "in vitro" and "in vivo" testing methodologies. They are fully capable of forming their own opinions as to the reliability of the UW Study.

**B. Ultreo's Non-Establishment Claims Are Expressly True.**

The non-establishment claims challenged by P&G as expressly false are literally truthful.

**1. The 4 Million Cycle Claim Is True.**

Ultreo's statement that the Ultreo toothbrush's "bristles create bubbles that are powerfully activated by nearly 4 million cycles of ultrasound energy" is literally true. Ultreo has measured and calculated the number of cycles of ultrasound energy generated by the Ultreo. McInnes Decl. ¶ 60 and Exhibit E. These calculations prove that the Ultreo generates approximately four million cycles of ultrasound energy per two minute brushing. This conclusion is corroborated by Dr. Crum. *See* Crum Decl. ¶ 11.

**2. Ultreo's "Sonic" Bristles Claim Is True.**

P&G also alleges that the following claim that Ultreo makes to consumers is expressly false: "Sonic action bristles with power tip creates bubbles and cleans away plaque upon contact." P&G asserts that this statement communicates to consumers that the "bubbles" remove plaque.

P&G's assertion is at odds with plain English meaning. The subject of the sentence is "Sonic action bristles," not "bubbles." Thus, a correct reading of the sentence is that the "sonic action bristles," not the "bubbles," are what will "clean away plaque by contact." This claim is undeniably true.<sup>7</sup>

**3. Ultreo's Reference To "Magic" Is Non-actionable Puffery.**

Ultreo uses the word "magic" in a letter to consumers that is contained in its product manual. Referring to the rubber waveguide that is nestled in the center of the product's brushhead, Ultreo states: this "is where the magic happens." Ultreo is merely pointing out the

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<sup>7</sup> To express the point that P&G claims exists, the sentence would have to read as follows: "Sonic action bristles with power tip create bubbles, which clean away plaque by contact." That is not, however, the claim being made by Ultreo.



location in the brushhead from where the ultrasound emanates. No consumer would ever read that statement literally and conclude that the product works by "magic." Gallagher Decl. ¶ 50.

Subjective or exaggerated claims about a product that cannot be proven true or false – i.e., "puffery" – are not actionable under the Lanham Act. *See Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 159-61 (2d Cir. 2007); *Lipton v. The Nature Co.*, 71 F.3d 464, 474 (2d Cir. 1995). This Court has held that the use of the term "magic" clearly amounts to non-actionable puffery. *See Dessert Beauty, Inc. v. Fox*, 05-Civ-3872, 2007 WL 2244870, at \*7 n.2 (S.D.N.Y. Aug. 6, 2007) (rejecting the assertion that an advertising claim regarding the "magical" capabilities of a product was misleading, because "[a]ny reasonable jury looking at this would understand that it was mere puffery . . .").

Indeed, P&G repeatedly employs the term "magic" in its advertising. For instance, P&G's website advertising for its Puffs Plus Tissues urges consumers to explore their "Magical Layer," claiming that magic is "[t]he secret behind what makes our tissues silkier than before – and more soothing for sore noses." Similarly, P&G urges consumers to "Discover all the Cleaning Possibilities" of its Mr. Clean "Magic" Eraser. Thus, P&G's argument in this regard is meritless and disingenuous in light of its own advertising practices. Gallagher Decl. ¶¶ 51-52.

#### **4. Ultreo's Reference To A "Feeling Of Clean" Is Truthful And Non-Actionable.**

P&G also criticizes Ultreo's "feeling of clean" claims, but falls far short of the mark in attempting to prove that those claims are expressly false.<sup>8</sup> A "feeling of clean" is what Ultreo reasonably believes its consumers will experience upon using its product. This is precisely what

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<sup>8</sup> Those claims include: (1) "Microbubbles are activated by the ultrasound and transformed into pulsating bubbles for an incredible feeling of clean"; or (2) "Ultreo is the first power toothbrush to combine ultrasound waveguide technology with precisely tuned sonic bristle action. Ultreo's bristles create microbubbles that are powerfully activated by a patented ultrasound waveguide. The result is an incredible, long-lasting feeling of clean." Gallagher Decl. ¶ 40.

the Consumer Use Survey, which is based on actual product usage, confirms. Sixty percent or more of all users indicated that they liked the Ultreo because it made their teeth feel "cleaner" or "smoother." Gallagher Decl. ¶¶ 19-21, 40-41. In any event, a "feeling of clean" is a subjective perception that is not actionable under the Lanham Act. *See The Gillette Co. v. Wilkinson Sword, Inc.*, 89-Civ-3586, 1989 WL 82453, at \*4 (S.D.N.Y. Jul. 6, 1989) (claim that shaver provided the "'smoothest, most comfortable shave possible'" is permissible as "mere 'puffing'") (citations omitted); *accord Maharishi Hardy Blechman Ltd. v. Abercrombie & Fitch Co.*, 292 F. Supp. 2d 535, 552-53 (S.D.N.Y. 2003).

Furthermore, "feeling of clean" oral care claims are hardly unique to Ultreo. Many oral care companies – including P&G – claim that their products provide consumers with a "feeling of clean" or similar sensation. For instance, P&G's advertisements for Scope claim that the mouthwash "leaves your breath feeling clean." Similarly, P&G's advertising for its Crest toothpastes claims that they "leave[] teeth feeling clean." Thus, P&G regularly makes the very type of subjective claim about which it now complains, without providing any objective substantiation. Gallagher Decl. ¶ 42.

**C. Ultreo's Claims Are Not False "By Necessary Implication".**

P&G is wrong when it contends that Ultreo's "feeling of clean" claims necessarily imply to consumers that the ultrasound feature removes plaque bacteria in the mouth. As the Second Circuit has declared, "'only an unambiguous message can be literally false.'" *DIRECTV*, 497 F.3d at 158 (citation omitted). Thus, the false by necessary implication doctrine does not apply, "if the language . . . is susceptible to more than one reasonable interpretation." *Id.*

Neither of the challenged statements about subjective "feeling[s] of clean" unambiguously communicates to consumers that ultrasound removes plaque bacteria. *See Hoffmann-La Roche*, 2006 WL 2588002, at \*28 (rejecting P&G's claim that website

advertisement claim was false by necessary implication); *see also Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 275 (4th Cir. 2002).

A "feeling of clean" connotes a sensation felt by a consumer's tongue after toothbrushing. It does not necessarily signify actual cleaning. Even if a "feeling of clean" did necessarily imply "clean," it does not necessarily also imply plaque removal. Teeth can be made clean by means other than through the removal of plaque, such as through the removal of food particles.

Hence, P&G must resort to extrinsic evidence to demonstrate that consumers are misled into believing that a "feeling of clean" means that plaque bacteria will be removed. However, P&G's consumer survey is so rife with flaws that P&G's claims of implied falsity also fail.

**D. Ultreo's Claims To Consumers Are Not Impliedly False.**

A plaintiff proceeding under a claim of implied falsehood *must* introduce extrinsic evidence, generally in the form of a consumer survey, to demonstrate what consumers understand the statement to mean. *See Johnson & Johnson \* Merck Consumer Pharms. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 297-98 (2d Cir. 1992); *Hertz Corp. v. Avis, Inc.*, 867 F. Supp. 208, 213 (S.D.N.Y. 1994). Moreover, a court may not substitute its own judgment or reaction to the advertisement's message for that of consumers. *Smithkline*, 960 F.2d at 297-98; *Hoffmann-La Roche*, 2006 WL 2588002, at \*26.

**1. The Results Of P&G's Consumer Survey Should Be Disregarded.**

"The evidentiary value of a survey's results rests upon the underlying objectivity of the survey itself." *Smithkline*, 960 F.2d at 300; *Coors Brewing Co. v. Anheuser-Busch Companies, Inc.*, 802 F. Supp. 965, 972 (S.D.N.Y. 1992). This objectivity, in turn, depends on whether the survey is "properly filtered to screen out those who got no message from the advertisement, whether the questions are directed to the real issues, and whether the questions are leading or suggestive." *Anheuser-Busch*, 802 F. Supp. at 972 (citations omitted).

Courts have been quick to dismiss the reliability of survey results where, as here, they are rife with methodological flaws. *See, e.g., Ortho Pharm. Corp. v. Cosprophar, Inc.*, 32 F.3d 690, 695-96 (2d Cir. 1994) (affirming district court's ruling regarding improperly conducted market surveys); *Hoffmann-La Roche*, 2006 WL 2588002, at \*27 (holding that P&G's survey was "so riddled with fundamental structural and implementation flaws" that it was inadmissible).

As Dr. Yoram Wind, Ultreo's marketing expert, explains, the results of the consumer survey P&G has conducted – based upon a few selected pages from Ultreo's website – should be rejected in their entirety. First, and most importantly, Dr. Dupont did not utilize a control group. In other words, Dr. Dupont did not test to see how many respondents reported an allegedly false message after reviewing the selected webpages *without* the alleged false or misleading statements. Without a control group, Dr. Dupont cannot say how many of the survey respondents are actually getting an allegedly false message from the advertising being challenged, as opposed to their preexisting beliefs or misconceptions. *See, e.g., Wind Decl.* ¶ 6.

"Controls are an essential feature of reliable survey evidence because they enable the surveyor to separate the wheat (the effect of the advertisement, alone, on the participant) from the chaff (the effect of 'the participant's prior knowledge and/or prior (mis)conceptions')". *Pharmacia Corp. v. GlaxoSmithKline Consumer Healthcare, LP*, 292 F. Supp. 2d 594, 601, 601-05 (D.N.J. 2003). Indeed, in *GlaxoSmithKline*, the court rejected a consumer survey conducted by Dr. Dupont because he did not adequately control for consumers' preexisting beliefs. *See also Hoffmann-La Roche*, 2006 WL 2588002, at \*24 (rejecting P&G's survey based, in part, on Dr. Wind's criticism that P&G used a disclaimer as a control, rather than purging the allegedly deceptive material from the advertisements); *Smithkline Beecham*, 960 F.2d at 301 (agreeing with Dr. Wind's criticism that a consumer survey was flawed in the absence of a control).

Second, Dr. Dupont's survey employed only leading questions, which makes the results invalid. *See AstraZeneca LP v. Tap Pharm. Products, Inc.*, 444 F. Supp. 2d 278, 292-93 (D. Del. 2006) (Dupont consumer survey of Internet advertisements ruled inadmissible since his "closed-ended question responses [were] . . . so lacking in reliability as to be effectively meaningless"); *Smithkline Beecham*, 960 F.2d at 300-01 (agreeing with Dr. Wind's criticism that a consumer survey employed leading questions). Indeed, if one considers the consumer responses to Dr. Dupont's first leading question, only 6% of the respondents considered the web pages to be communicating the ability of ultrasound to remove plaque bacteria. Dupont Decl., Exh. A, ¶ 12. This falls far short of the 20-25% threshold usually required to prove consumer misperception. *See Johnson & Johnson \* Merck Consumer Pharms. Co. v. Rhone-Poulenc Rorer Pharms., Inc.*, 19 F.3d 125, 134 n.14 (3d Cir. 1994); *R.J. Reynolds Tobacco Co. v. Loews Theatres, Inc.*, 511 F. Supp. 867, 876 (S.D.N.Y. 1980).

Indeed, even if the Dupont survey were presumed valid, P&G's claim of implied falsity still fails because the implied claim is true. Valid laboratory tests have demonstrated that Ultreo's ultrasound can remove plaque bacteria. McInnes Decl. ¶¶ 17-21; Berg Decl. ¶ 35.

## **II. P&G WILL NOT SUFFER IRREPARABLE HARM.**

A motion for a preliminary injunction will not be granted in the absence of a showing of irreparable harm. *See Rodriguez v. DeBuono*, 175 F.3d 227, 234 (2d Cir. 1999); *Bell & Howell: Mamiya Co. v. Masel Supply Co. Corp.*, 719 F.2d 42, 45 (2d Cir. 1983). Indeed, "[t]he likelihood of injury and causation . . . must be demonstrated in some manner." *DIRECTV, Inc.*, 497 F.3d at 161 (citation omitted). P&G must demonstrate "a logical causal connection between the alleged false advertising and [its] own sales position." *McNeil-PPC, Inc. v. Pfizer, Inc.*, 351 F. Supp. 2d 226, 247 (S.D.N.Y. 2005) (citation omitted).



Tacitly acknowledging its inability to demonstrate irreparable injury, P&G seeks to avail itself of a presumption of irreparable harm that clearly does not apply to this case. The Second Circuit has held that a false comparative advertising claim which mentions the competitor by name will be presumed to give rise to irreparable injury. *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 62 (2d Cir. 1992). In *DIRECTV*, the Court extended this presumption to false comparative advertisements that do not mention the plaintiff by name, but unmistakably point to the plaintiff's product in the mind of the consumer. *Id.*, 497 F.3d at 161-62 (claim that satellite television picture is superior to that supplied by cable clearly refers to the local cable company). However, here there is no comparative advertising claim. None of Ultreo's advertisements claims that its product is superior to Oral-B, or refers expressly or impliedly to Oral-B. The presumption simply does not apply here.

P&G's attempt to establish the harm it will suffer actually belies its claim of irreparable injury. As Dr. Mohan Rao, Ultreo's economics expert, explains, all of the harm claimed by P&G in this case is easily quantifiable. See Declaration of Mohan Rao ¶¶ 25-26. Where, as here, a party's claimed damages are quantifiable, its claim of irreparable harm must fail. See *Kamerling v. Massanari*, 295 F.3d 206, 214 (2d Cir. 2002); *DeBuono*, 175 F.3d at 234); *CollaGenex Pharms., Inc. v. IVAX Corp.*, 375 F. Supp. 2d 120, 124 (E.D.N.Y. 2005).

P&G's claim of irreparable harm fails for other reasons as well. P&G has unequivocally failed to establish, as it must, "a logical causal connection between the alleged false advertising and its own sales position." *Pfizer*, 351 F. Supp. 2d at 247; Rao Decl. ¶¶ 27-30; see also *DIRECTV*, 497 F.3d at 162; *B. Sanfield, Inc. v. Finlay Fine Jewelry Corp.*, 258 F.3d 578, 580-81 (7th Cir. 2001).

P&G contends that the entry of the Ultreo into the market will adversely affect its sales. P&G Brief at 24. However, the pertinent issue is not whether Ultreo's entry into the market will

impact P&G. Any sales lost by P&G to a new market entrant are the result of lawful, healthy competition. Instead, P&G must – but has failed to – distinguish between the lost sales it believes it would sustain from the alleged false advertising, from any lost sales it would experience from lawful competition (i.e., truthful advertising) by Ultreo. Rao Decl. ¶ 20.

Moreover, any lost sales alleged by P&G are *de minimus*. Rao Decl. ¶ 31. P&G's robust position in the premium power toothbrush market and its concomitant healthy sales refute its claim of irreparable injury, especially when compared to the fledgling market status of Ultreo. *See, e.g., Creative Labs, Inc. v. Mad Dog Multimedia, Inc.*, No. 02-Civ-4575, 2002 WL 32068970, at \*3 (N.D. Cal. Oct. 3, 2002) ("substantial disparity" in market shares undermines showing of irreparable injury); *see also Frank's GMC Truck Center, Inc. v. Gen. Motors Corp.*, 847 F.2d 100, 102 n.4 (3d Cir. 1988); *Licata & Co. Inc. v. Goldberg*, 812 F. Supp. 403, 407 (S.D.N.Y. 1993). By any measure, Ultreo's alleged projected sales barely register a blip on the radar screen of P&G's \$76 billion sales empire.

P&G's arguments regarding irreparable injury to the public are similarly groundless. The efficacy of the Ultreo in removing plaque, reducing gingivitis, and reducing extrinsic stains on teeth has been unequivocally established in a clinical context. Nowhere in its papers does P&G challenge the results of these clinical studies. These studies, conducted in conjunction with a leading independent clinical research facility frequently used by P&G and others, demonstrate that the Ultreo is safe and effective. McInnes Decl. ¶¶ 9-15; Berg Decl. ¶¶ 7-8. Thus, P&G's claim that the public safety is at risk, or that the public interest favors injunctive relief, is specious. *See Hoffmann-La Roche*, 2006 WL 2588002, at \*10. ("P&G's chief concern is not public health and safety, but rather its market share").

Furthermore, P&G's delay in seeking injunctive relief shows the absence of any irreparable injury. *See Citibank, N.A. v. Citytrust*, 756 F.2d 273, 276-77 (2d Cir. 1985) (finding



that 10 week delay in seeking a preliminary injunction, where plaintiff knew that the defendant intended to enter the market, "undercut[] the sense of urgency that ordinarily accompanies a motion for preliminary relief and suggests that there is, in fact, no irreparable injury"); *accord Tough Traveler, Ltd. v. Outbound Prods.*, 60 F.3d 964, 968 (2d Cir. 1995); *Total Control Apparel, Inc. v. DMD Int'l Imports, LLC*, 409 F. Supp. 2d 403, 408 (S.D.N.Y. 2006).

P&G first complained about Ultreo's advertising in March 2007, asserting that clinical studies were required to support any ultrasound-related advertising claims. Yet, it was not until late September 2007 – a full 6 months later – that P&G commenced this action. *See* Declaration of Marc C. Levy ¶¶ 3-15; Gallagher Decl. ¶¶ 24-27.

Courts have refused to grant preliminary injunctive relief where a party's delay in bringing suit is far less than the long delay present in this case. *See, e.g., Magnet Communications LLC v. Magnet Communications, Inc.*, No. 00-Civ-5746, 2001 WL 1097865, at \*1 (S.D.N.Y. Sept. 19, 2001 ) (delay of 12 weeks); *ImaginOn*, 90 F. Supp. 2d at 350 (delay of 18 weeks); *The Comic Strip, Inc. v. Fox Television Stations, Inc.*, 710 F. Supp. 976, 981 (S.D.N.Y. 1989) (delay of 3 months).

### **III. THE BALANCE OF HARDSHIPS WEIGHS AGAINST INJUNCTIVE RELIEF.**

P&G does not argue that such a balance weighs in its favor – nor can it. Ultreo has everything to lose if P&G's request for a preliminary injunction is granted, while P&G's dominant market position will continue unabated regardless of how this motion is decided.

Ultreo, which employs 140 people and manufactures a single product, started production this year.

Contains Information Designated As  
"Confidential" Pursuant To November 9,  
2007 Stipulated Confidentiality Order In  
This Action

**REDACTED**

Gallagher Decl. ¶¶ 22, 28-33.

In contrast, by P&G's own admission, Ultreo can be expected to obtain less than one-quarter of one percent of the market share for toothbrushes. Ultreo's sales during the pendency of this litigation are plainly inconsequential to P&G. These facts tip the balance of the hardships decidedly in Ultreo's favor. *See L&F Products*, 845 F. Supp. at 1004 (refusing to grant preliminary injunction where the commercials were an integral part of a product launch); *Autoinfo, Inc. v. Hollander Publ'g Co., Inc.*, No 90-Civ-6994, 1991 WL 64190, at \*2 (S.D.N.Y. Apr. 17, 1991) (issuance of preliminary injunction not favored where effect will be to prevent enjoined party from conducting its business); *see also Duraco Prods. v. Joy Plastic Enters. Ltd.*, 822 F. Supp. 1202, 1211 (W.D. Pa. 1993) (refusing to grant preliminary injunction where defendants "stand to lose their entire business if they are enjoined," while the plaintiff "carries many other product lines"), *aff'd*, 40 F.3d 1431 (3d Cir. 1994).

#### **IV. P&G'S MOTION SHOULD BE DENIED IN LIGHT OF ITS UNCLEAN HANDS.**

Parties who engage in the same form of commercial conduct about which they complain are not entitled to injunctive relief. *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245 (1933). In short, he who seeks equity must first do equity. *In re Estate of Klotz*, 52 F.3d 398, 404 (2d Cir. 1995); *In re Northwestern Airlines Corp.*, 366 B.R. 270, 274 (S.D.N.Y. 2007).

P&G has engaged in the very same types of conduct about which it complains in this pretextual litigation. P&G has, for instance, made advertising claims about its own oral care products based solely on laboratory studies; has extolled the benefits of beyond-the-bristles cleaning as shown in laboratory studies; and regularly makes "feeling of clean[]" advertising claims, or claims that use the word "magic." In light of these actions, P&G's motion should be denied on the basis of its unclean hands. *See Haagen-Dazs, Inc. v. Frusen Gladje Ltd.*, 493 F.

Supp. 73, 76 (S.D.N.Y. 1980); *Emco, Inc. v. Obst*, CV03-6432-R, 2004 WL 1737355, at \*\*5-6 (C.D. Cal. Jul. 29, 2004).

**CONCLUSION**

P&G is not likely to prevail on the merits of its claims; no public safety issues are implicated; the public interest favors increased, and not diminished, competition; and the balance of the equities weighs decidedly in favor of Ultreo. For all these reasons, Ultreo respectfully requests that P&G's motion be denied.

Dated: November 30, 2007  
New York, New York

**Respectfully submitted,**

**WINSTON & STRAWN LLP**

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**CERTIFICATE OF SERVICE**

I hereby certify under penalty of perjury that on November 30, 2007, I caused a copy of the foregoing **REDACTED MEMORANDUM OF LAW IN OPPOSITION TO THE PROCTER & GAMBLE COMPANY'S MOTION FOR A PRELIMINARY INJUNCTION** to be served upon counsel for The Procter & Gamble Company by the Court's ECF Filing System and by hand delivery to the following individual:

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**Attorneys for The Procter & Gamble Company**

Dated: New York, New York  
November 30, 2007

  
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Lina M. Viviano